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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,238	09/12/2003	Rene Verdonk	920522-94798 6848	
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BARNES & THORNBURG P.O. BOX 2786			ALI, SHUMAYA B	
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			. 3743	
		DATE MAILED: 04/18/2005		

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary		Application No.	Applicant(s)		
		10/661,238	VERDONK ET AL.		
		Examiner	Art Unit		
		Shumaya B. Ali	3743		
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
THE I - Exter after - If the - If NO - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. Insions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. In period for reply specified above is less than thirty (30) days, a reply of period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).		
Status					
1)🖂	Responsive to communication(s) filed on 12 Se	eptember 2003.			
2a) <u></u> □	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.				
3)	☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Dispositi	on of Claims				
5)□ 6)⊠ 7)⊠	Claim(s) <u>1-18</u> is/are pending in the application.  4a) Of the above claim(s) <u>7 and 13</u> is/are withdough Claim(s) is/are allowed.  Claim(s) <u>1,3-6,8-10 and 14-18</u> is/are rejected.  Claim(s) <u>2,11 and 12</u> is/are objected to.  Claim(s) are subject to restriction and/or	rawn from consideration.			
Applicati	on Papers				
10)	The specification is objected to by the Examiner The drawing(s) filed on is/are: a) access applicant may not request that any objection to the Replacement drawing sheet(s) including the correction to the oath or declaration is objected to by the Example 2.	epted or b) objected to by the Edrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).		
Priority ι	ınder 35 U.S.C. § 119				
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
2)	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: detailed action	ate atent Application (PTO-152)		

#### **DETAILED ACTION**

#### Election/Restrictions

1. Applicant's election with traverse of species 1, sub-species 1b in the reply filed on 2/17/2005 is acknowledged. The traversal is on the ground(s) that the embodiment shown in figures 6 and 10 is essentially the same, as the embodiment of figure 4 (lines 5-10) is found persuasive. Figures 6 and 10 will be considered for examination.

# Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
- 3. Claim 11 recites the limitation "said support" on page 24, line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 11 depends from claim 1, which does not positively recite or provide proper antecedent basis to "said support" disclosed in claim 11.

# Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,3-5,9-10,and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saringer et al. US Patent 5,738,636.

- 5. As to claim 1, Saringer et al. disclose a portable (web dictionary definition of portable is something capable of being transferred from one place to another; Saringer's brace is considered portable since the brace has strap members, see fig.1a reference objects 28,30, and 80 that secures the brace to a wearer so that the brace can be carried or transferred from one place to another) device suitable for providing continuous passive motion of a limb comprising (see col.1 lines 6-9): a brace (see fig.1a reference object 20) for supporting a distal end (26) (see fig.1a reference object 44, col.4 lines 44-46) of said limb; a drive mechanism (see fig.1a reference object 42) for providing a settable continuous passive motion of said limb, said drive mechanism being coupled to said brace and controlling movement of said distal end (26) of the limb characterized in that said passive motion is controlled in a first control point (see fig.5, position of the actuator to control ulnar/dadial deviation is considered "a first control point", col.6 lines 46-48) and a second control point (see fig.6, position of the actuator to control pure extension and flexion motion is considered "a second control point", col.6 lines 48-49) on said distal end (26) of said limb; and said drive mechanism comprises at least a first unit (see fig.1a reference object 70) for controlling movement of said first control point of said distal end (26) of said limb.
- 6. As to claim 3, Saringer et al. disclose a portable device according to claim 1, furthermore comprising means for immobilizing (see fig.1a reference object 48, col.4 lines 36-38) said second control point of said distal end (26) of said limb.
- 7. As to claim 4, Saringer et al. disclose a portable device according to claim 1 wherein said portable device furthermore comprises flexible positioning means (7) (see fig.1a reference object 44) provided with a fastening means (see fig.1a reference object 30) positioning said brace and said drive

mechanism on the body of a patient carrying said device in a stable position (a stable position is obtained when the fastening means are used to securely position the hand/wrist relative to the body of a wearer), whereby said drive mechanism is at least partially housed (see col.4 lines 43-46) within said positioning means (7).

- 8. As to claim 5, Saringer et al. disclose a portable device according to claim 1, wherein said drive mechanism for providing a settable continuous passive motion of said limb is a motor (31) (see fig.1a reference object 42), however do not disclose a "programmable" motor in figure 1a. However, Saringer's figure 12 discloses a brace with a controller provided with an on/off button to provide an ankle (joint) movement and the range of movement (which is activated by a motor) is controlled by programming an actuator (see col7 lines 55-64). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the motor in figure 1a in view of figure 12 in order to include a programming motor for the purposes of limiting or controlling the range of motion of a joint (wrist).
- 9. As to claim 9, Saringer et al. disclose a potable device according to claim 1, wherein said support of the distal end (26) of the limb of said brace is furthermore provided with a limb fastener (10) (see fig.1a reference object 80), and said support of the proximal end (25) of the limb of said brace is furthermore provided with a limb fastener (10) (see fig.1a reference object 28).
- 10. As to claim 10, Saringer et al. disclose a potable device according to claim 9, wherein said fasteners for the distal end (26) and the proximal end (25) of the limb comprise fixing straps (12) (see fig.1a reference objects 80 and 28, col.4 lines 24 and 65; hook and loop type straps are considered fixing straps since they are capable of fixing the device to a wearer in a secure position).

- 11. As to claim 14, Saringer et al. disclose a portable device according to claim 4, wherein the positioning means (7) further comprises belts (see fig.1a reference object 30, a strap is considered an equivalent of a belt since they are both capable of securing the device to a body) provided with fasteners (the hook and loop, see col.4 line 24 configuration of the strap are considered fasteners), for positioning said device on a body.
- 12. **As to claim 15, Saringer et al. disclose** a portable device according to claim 1 further comprising a remote control unit (19) (see fig.1a reference object 56) for controlling the passive movements provided by the device
- As to claim 16, Saringer et al. disclose a potable device according to claim 15, wherein said remote control unit (19) comprises control switches (see fig.1a reference object 59), however do not disclose a visual display screen, however, Saringer's figure 12 discloses a brace with a controller, more specifically a front panel which is considered "a visual display screen" for indicating whether the user has started (as indicated by a hand symbol in fig.12) or stopped (as indicated by another symbol next to a stop label) a program for controlling a joint movement. The user depresses switch (204) to provide ankle (joint) movement and when the switch is released to stop actuator or to program the range of motion (see col7 lines 55-64). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the controller in figure 1a in view of figure 12 in order to include a visual display screen for the purposes of allowing the user to have a visual representation of the type of program that is being set or adjusted to limit the range of motion for a joint (wrist) movement.
- 14. As to claim 17, Saringer et al. do not disclose a potable device according to claim 1, further comprising two connectors (20) (21), provided at the upper side of the device, whereby one connector is

Application/Control Number: 10/661,238

Art Unit: 3743

connected to the remote control unit (19) and the other connector is connected to an electric transformer (28) or one or more batteries (27), however Saringer's fig.9 discloses two connectors (see fig.9 connectors at the upper side of reference object 180,see col.7 lines 47-54), provided at the upper side of the device, whereby one connector is connected to the remote control unit (see fig.9 a line/wire connecting one of the controller to reference object 202) and the other connector is connected to an electric transformer (see fig.1 a second line/wire connecting the other controller to a transformer, 206 via 200) or one or more batteries (see col.7 lines 50-52). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in fig.1a in view of fig.9 in order to provide two connectors for the purposes of providing power supplies via a transformer to the control units to further control the operation of the device.

As to claim 18, Saringer et al. disclose a portable device according to claim 1, wherein the passive limb movements provided by the device are provided in an automated way (the limitation is considered an expected result of a device providing continuous passive motion. The movement is considered "automated" since it is machine driven, see col.1 lines 12-17 and col.2 lines 24-25).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saringer et al. US Patent 5,738,636 in view of Funk et al. US Patent 4,651,719.

As to claim 6, Saringer et al. disclose a portable device according to claim 1 wherein the brace comprises a support (see fig.1a reference object 70) for said distal end (26) of the limb comprising a first primary sub-frame (3) (see fig.1a reference object 70) for supporting said distal end (26) of the limb, a support (see fig.1a reference object 22) for said proximal end (25) of said limb comprising a second primary sub-frame (4) (see fig.1a reference object 22) for supporting said proximal end (25) of the limb,

Application/Control Number: 10/661,238

**Art Unit: 3743** 

support for said proximal end (25) of the limb. As to claim 6, Funk et al. teach a device providing a continuous passive motion to a shoulder with an upper arm support that is hinged to a base (see col.2 lines 42-49). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the device of Saringer et al in for the purposes of providing movement between two support members with a hinge joint as taught by Funk et al.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saringer et al. US Patent 5,738,636 in view of Backman US Patent 5,236,411.

As to claim 8, Saringer et al. disclose a portable device according to claim 4, wherein said housing is provided with a fastening means (see fig.1a reference object 30), however do not disclose said positioning means (7) comprises an inflatable housing of flexible material provided with a fastening means, said housing allowing at least partial deformation when fastened on a body for providing a stable position. As to claim 8, Backman teaches a device for elevating a limb of a patient which comprises an inflatable member that is adjustable between a deflated state and an inflated state and a harness for attaching the device to the body of a patient. The member is placed between a support surface and the limb of a patient, thus elevating the limb (see Backman abstract). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the device of Saringer et al. in view of Backman in order to provide an inflatable housing for the purposes of providing adjustment and elevation of a person's limb with respect to the body.

## Claim Objections

Page 8

- 18. Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 11 recites the limitation "said support" on page 24, line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 11 depends from claim 1, which does not positively recite or provide proper antecedent basis to "said support" disclosed in claim 11. Since the metes and bounds of the claimed limitation are vague, the claimed subject matter is not considered for examination.
- 19. Claim 14 is objected to because of the following informalities: claim 14 recites the limitation "belts", whereas the elected figures clearly disclose the positioning means comprises a belt. Appropriate correction is required.

### Allowable Subject Matter

Claims 2 and 12 are objected to as being dependent upon a rejected base claim, but would be 20. allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

# **Priority**

21. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 02447173.2, filed on 9/12/2002.

#### Information Disclosure Statement

22. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A (1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

#### Conclusion

- 23. The prior art made of record on form PTO-892 and not relied upon shows orthopedic device capable of providing continuous positive motion.
- 24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Shumaya B. Ali** whose telephone number is **571-272-6088**. The examiner can normally be reached on M-F 8:30 am-4: 30 pm.
- 25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Henry Bennett** can be reached on **571-272-4791**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-6088.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit 3743

Supervisory Fatent Examiner